

## **REMARKS**

### **Status of the Claims**

Claims 1-5 are pending in the application. Claims 1-5 have been rejected.

Reexamination and reconsideration of the claims is respectfully requested in light of the following arguments.

### **The Double Patenting Rejection Should be Withdrawn**

Claims 1 and 3 have been rejected by the Examiner under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 26 of USP 6,391,026 to Hung. The Examiner states that the Hung patent recites the same method of treating a breast comprising vibration to the duct. The Applicants disagree. Hung recites a method of treating a breast duct by transferring energy to or from cells lining the duct in an amount sufficient to ablate or inhibit proliferation of said cells.

The method of the present invention describes a method for increasing a retrievable cell amount in a breast duct. The two methods have diametrically opposed purposes. The Hung patent teaches a method of ablating or damaging cells. The present invention teaches a method of obtaining intact cells from a breast duct for the purpose of further analysis. One skilled in the art would not look to the teaching of Hung for a method of retrieving intact cells from a breast duct. Thus, Claim 1 of the present invention and Claim 26 of the Hung patent are patently distinct. Withdrawal of the rejection is requested.

**The Rejections Under 35 U.S.C. §102(b) Should be Withdrawn**

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,255,327 ("Endo").

The Examiner argues that since Claim 1 can be interpreted very broadly, the Endo vibration device when applied to the breast would inherently provide the desired result of the method claim. The Applicants disagree.

Claim 1 of the present invention recites a method for increasing a retrievable cell amount in a breast duct comprising the steps of applying vibration to a breast duct sufficient to induce cell sloughing within the breast duct and collecting the sloughed cells from the breast duct. All of the limitations of a claim must be considered when judging the patentability of the claim against the prior art. *In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970). There is no teaching or suggestion in Endo of a method of applying vibration to a breast duct sufficient to induce cell sloughing within the breast duct and then collecting the sloughed cells from the breast duct. Since Endo makes no mention of collecting cells from a breast duct, Endo cannot anticipate Claim 1. Since Claim 3 contains all of the limitations of Claim 1, Endo therefore cannot anticipate Claim 3 either. Withdrawal of the rejection is requested.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,255,327 ("Brenden").

The Examiner once again argues that since claim 1 can be interpreted very broadly, the Brenden vibration device when applied to the breast would inherently provide the desired result of the method claim. The Applicants disagree.

Claim 1 of the present invention recites a method for increasing a retrievable cell amount in a breast duct comprising the steps of applying vibration to a breast duct sufficient to induce cell sloughing within the breast duct and collecting the sloughed cells from the breast duct. The Examiner suggests that Endo meets all the limitations of the present claims. The applicant respectfully disagrees. The Examiner states that "...the Endo vibration device when applied to the breast (col. 2, lines 67-68) would inherently provide the desired result of the method claim (even if very limited)." See page 6, lines 1-12. The Applicants respectfully disagree.

To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently. See Glaxo Inc. v. Novopharm Ltd., 52 F.3d 1043, 1047, 34 USPQ2d 1565, 1567 (Fed. Cir. 1995). Endo does not teach or suggest a method of applying vibration to a breast duct sufficient to induce cell sloughing within the breast duct and then collecting the sloughed cells from the breast duct. Since Brenden makes no mention of collecting cells from a breast duct, Brenden cannot anticipate Claim 1. Since Claim 3 contains all of the limitations of Claim 1, Brenden therefore cannot anticipate Claim 3 either. In view of the forgoing, Applicants respectfully request that the Examiner withdraw the pending rejections under 35 U.S.C. §102(b).

**The Rejection under 35 USC 103(a) over Hung in view of Endo Should be**

**Withdrawn**

Claims 1-5 were rejected under 35 U.S.C. § 103(a) over U.S. Patent No. 6,413,228 ("Hung") in view of U.S. Patent No. 5,255,327 ("Endo"). This rejection is respectfully traversed.

Applicants respectfully traverse the foregoing rejection on the grounds that the Examiner has failed to establish a prima facie case of obviousness, since neither Hung or Endo, either alone or in combination, fail to teach or suggest the claimed invention and further fail to provide the necessary motivation or expectation of success for the ordinarily skilled artisan to arrive at the claimed invention.

To establish a prima facie case of obviousness, it is necessary for the Examiner to present evidence, preferably in the form of some teaching, suggestion, incentive or inference in the applied references, or in the form of generally available knowledge, that one having ordinary skill in the art would have been motivated to make the claimed invention and would have had a reasonable expectation of success in making the claimed invention. Under section 103, "[b]oth the suggestion and the expectation of success must be founded in the prior art, not in applicant's disclosure" (Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd. 927 F.2d 1200, 1207, 18 USPQ2d 1016 (Fed. Cir. 1991), quoting In re Dow Chemical Co., 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed Cir. 1988)).

Moreover, when a combination of references are used to establish a prima facie case of obviousness, the Examiner must present evidence that one having ordinary skill in the art would have been motivated to combine the teachings in the applied references in

the proposed manner to arrive at the claimed invention. See, e.g., *Carella v. Starlight Archery*, 804 F.2d 135, 231 USPQ 644 (Fed. Cir. 1986); and *Ashland Oil, Inc. v. Delta Resins and Refractories, Inc.*, 776 F.2d 281, 227 USPQ 657 (Fed. Cir. 1985).

Applying this standard to the references cited by the Examiner, it is clear that the Examiner has failed to meet the burden of providing evidence of a motivating force sufficient to impel a person of ordinary skill in the art to use the method of the present invention. None of the above references cited by the Examiner describes a method for increasing a retrievable cell amount in a breast duct comprising the steps of applying vibration to a breast duct sufficient to induce cell sloughing within the breast duct and collecting the sloughed cells from the breast duct as recited in Claim 1. In fact, none of these references discloses a method of applying vibration to a breast for the purpose of collecting cells sloughed off by the vibration. Endo merely describes a “vibrostimulative device” to “...to provide comforts to the subject.” As described in the patent, the device is used to “...vibrate the whole body or a relatively large body area of the subject.” The device of Endo is basically a massage device. One having ordinary skill in the art would not have been motivated to make the claimed invention by looking at the vibrostimulative device of Endo.

The Examiner argues that “...fast massaging of the breast would provide some vibration.” The Applicants disagree. Massaging or rubbing is not applying vibration to a duct.

Applicants respectfully submit that the Examiner has not provided any motivation to combine the vibrostimulative device of Endo with the methods, devices and systems for collecting breast ductal fluid described in Hung to arrive at the claimed invention.

Withdrawal of this rejection under 35 USC 103(a) is respectfully requested.

### **Dependent Claims**

The Examiner rejected dependent claim 2-5 under 35 U.S.C. § 103(a) over U.S. Patent No. 6,413,228 ("Hung") in view of U.S. Patent No. 5,255,327 ("Endo"). The dependent claim 2 limits the scope of the vibration to ultrasound. Neither Hung nor Endo teach or suggest the use of ultrasound sufficient to induce cell sloughing within a breast duct.

Likewise, dependent claim 3, which has the limitation of applying vibration to a breast duct either externally or internally; dependent claim 4, which has the limitation of vibration combined with heat and/or massage; and dependent claim 5, which has the limitation of collecting a retrievable cell amount is collected through ductal lavage; were all rejected under 35 U.S.C. § 103(a), yet the Examiner has not pointed to any teaching or suggestion within Hung nor Endo to anticipate these limitations. Clearly, dependent claims 2-5 are not anticipated by Hung nor Endo. Withdrawal of the rejection is requested.

### **CONCLUSION**

In light of the arguments presented above, Applicants respectfully submit that the claims are in condition for allowance. Early notice to this effect is solicited.

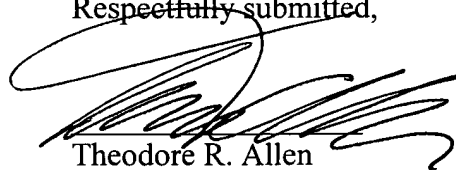
It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR

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§ 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 502855 referencing attorney docket number 12.023011-CIP.

Customer No. 0000 38732

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Theodore R. Allen', is written over the printed name.

Theodore R. Allen  
Registration No. 41,578  
Tel: 508-263-8490  
**Cytoc Corporation**  
250 Campus Drive  
Marlborough, MA 01752  
Tel (508) 263-8490  
Fax (508) 263-2959